IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

JULIE TUTTLE, Plaintiff, v. DEXCOM, INC., Defendant.	:	CIVIL ACTION NO. 1:20-CV-4744-LMM

ORDER

This case comes before the Court on Defendant Dexcom, Inc.'s Motion for Judgment on the Pleadings [27]. After due consideration, the Court enters the following Order:

I. BACKGROUND

Plaintiff Julie Tuttle alleges that Defendant Dexcom, Inc. ("Dexcom") caused the death of her husband, Michael Paul Tuttle. Dkt. No. [16].[1] Mr. Tuttle died when he suffered a hypoglycemic event in his sleep. At the time, he was using a Dexcom G6 Continuous Glucose Monitoring System ("G6 System") to monitor his blood sugar. Plaintiff alleges that the G6 System malfunctioned and

[1] Except where otherwise indicated, the facts in this section are drawn from the Amended Complaint, Dkt. No. [16], and viewed in the light most favorable to Plaintiff, the non-moving party.

failed to report the hypoglycemic event, so Mr. Tuttle was not aware of the event and could not address it before his blood sugar fell to fatal levels. Because Dexcom designed, manufactured, and marketed the G6 System, Plaintiff alleges that Dexcom is responsible for the failure of the G6 System and consequently for Mr. Tuttle's death.

Based on these allegations, Plaintiff has filed an Amended Complaint which includes five counts: Count One – Strict Liability; Count Two – Negligence; Count Three – Breach of Warranty; Count Four – Wrongful Death; and Count Five – Punitive Damages. Dkt. No. [16]. Within the claims for strict liability and negligence, Plaintiff alleges design defects, manufacturing defects, and failure to warn based on marketing/packaging defects. Id. ¶¶ 88, 105. The Court addresses the specific allegations pertinent to these claims in further detail below.

Dexcom seeks judgment on all of Plaintiff's claims because, it argues, they are preempted by federal law and because they are otherwise inadequately pled. Dkt. No. [27]. Dexcom argues that Plaintiff's claims are preempted by the United States Food and Drug Administration's ("FDA") regulations which apply to the G6 System. That argument requires the Court to consider in some detail the FDA's regulations and the federal laws that enable them, so the Court briefly describes the relevant legislation and rulemaking:

The FDA began regulating medical devices in 1976 when Congress passed the Medical Device Amendments of 1976 ("MDA") to the Food, Drug, and

Cosmetic Act ("FDCA"), 21 U.S.C. § 360c *et seq*. Through the MDA, Congress sought to create for medical devices a uniform nationwide regulatory scheme at a time when several states had begun to adopt their own regulatory measures. To advance this goal, the MDA included an express preemption provision that displaces state regulations:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a). The exception in subsection (b) is not at issue here. As discussed below, the Supreme Court's interpretation of this provision has shaped the preemptive scope of FDA regulations. That scope is essential to determine preemption in this case.

The MDA also grouped medical devices into three classes based on risk to human health. Class I includes relatively low-risk devices subject only to the "general controls" applicable to all medical devices. 21 U.S.C. § 360c(a)(1)(A). General controls "include provisions that relate to adulteration; misbranding; device registration and listing; premarket notification; banned devices; notification, including repair, replacement, or refund; records and reports; restricted devices; and good manufacturing practices." United States Food & Drug Administration, General Controls for Medical Devices (2018),

https://www.fda.gov/medical-devices/regulatory-controls/general-controls-medical-devices. Class I includes, for example, plastic bandages and examination gloves. Riegel v. Medtronic, 552 U.S. 312, 316 (2008).

Class II includes devices for which general controls are inadequate to assure safety and effectiveness, but which the FDA deems reasonably safe and effective with "special controls." 21 U.S.C. § 360c(a)(1)(B). Special controls are usually device-specific regulations, and they include "performance standards, postmarket surveillance, patient registries, development and dissemination guidelines . . . , [and] recommendations." Id. Class II devices include powered wheelchairs and surgical drapes, Riegel, 552 U.S. at 317, as well as the device at issue in this case, the Dexcom G6 System.

Class III includes the riskiest devices, and devices in this category have two relevant attributes. First, for Class III devices, the general and special controls deemed adequate for the lower classes are inadequate. 21 U.S.C. § 360c(a)(1)(C). And second, Class III devices must either (1) be "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health" *or* (2) "present[] a potential unreasonable risk of injury[.]" Id. Among Class III devices are pacemakers and balloon catheters.

While the Dexcom G6 System is not a Class III device, the regulatory pathways for such devices are relevant here. The Supreme Court's MDA preemption cases have involved Class III devices and have evaluated preemption

based on which regulatory pathways the Class III devices followed to approval. Two pathways are especially important because, as discussed further below, the parties appeal to the Supreme Court's cases involving these pathways in their disagreement over preemption.

First, the MDA provides a regulatory pathway called "premarket approval" in which Class III devices undergo "rigorous" testing. 21 U.S.C. § 360e; Riegel, 552 U.S. at 317–18. Premarket approval requires that applicants submit multivolume applications that include "among other things, full reports of all studies and investigations of the device's safety and effectiveness . . . ; a 'full statement' of the device's 'components, ingredients, and properties and of the principle or principles of operation'; 'a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and when relevant, packing and installation of such device'; samples or device components required by the FDA; and a specimen of the proposed labeling." Riegel, 552 U.S. at 318 (citing 21 U.S.C. § 360e(c)(1)).

After receiving material from an applicant, the FDA sets out to determine whether the safety and effectiveness of a device can be reasonably assured. Id. § 360e(d). The FDA must "weig[h] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." Id. § 360c(a)(2)(C). During premarket approval, the FDA may refer an application to a panel of outside experts, 21 C.F.R. § 814.44(a) (2007), and may request additional data from the manufacturer, 21 U.S.C. § 360e(c)(1)(G). In all,

premarket approval requires an average of 1,200 hours of work by the FDA. Riegel, 552 U.S. at 318 (citing Medtronic v. Lohr, 518 U.S. 470, 477 (1996)). After this review, the FDA grants or denies premarket approval. If a device is approved, "the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." 21 U.S.C. § 360e(d)(6)(A)(i).

The second path to approval for a Class III device is not this rigorous risk-based review, but rather a test for "substantial equivalence." The pathway based on substantial equivalence was created as an alternative to premarket approval. When the MDA was passed, it grandfathered in devices already on the market until the FDA could fully approve those devices. Id. §§ 360c(f)(1), 360e(b)(1). But Congress did not want to create a competitive advantage for those grandfathered devices by excluding competitive devices of the same type. Lohr, 518 U.S. at 478 (describing the purpose of substantial equivalence: "to prevent manufacturers of grandfathered devices from monopolizing the market while new devices clear the PMA hurdle"). So Congress empowered the FDA to approve devices that could show substantial equivalence to another device exempt from premarket approval. Id. § 360c(f)(1)(A). Courts often refer to the substantial equivalence pathway by its statutory section, § 510(k). Riegel, 552 U.S. at 317 ("The agency's review of devices for substantial equivalence is known as the § 510(k) process, named after the statutory provision describing the review.").

The regulatory pathway at issue in this case is neither premarket approval nor § 510(k) substantial equivalence. Instead, it is undisputed that the Dexcom G6 System was approved through a "De Novo classification" request. Dkt. No. [16] ¶ 44. This avenue is available to a new device entering the market with no substantially equivalent predicate but when the FDA determines that "general and special controls [] provide reasonable assurance of safety and effectiveness for the intended use . . . ." United States Food & Drug Administration, De Novo Classification Requests (2019), https://www.fda.gov/medical-devices/premarket-submissions/denovo-classification-request. In other words, De Novo classification allows a device to enter the market as a Class I or II device, avoiding altogether the premarket approval/substantial equivalence fork that ordinarily sorts Class III devices.

As previously mentioned, Dexcom argues that Plaintiff's state tort claims are preempted by virtue of the G6 System's De Novo classification. Dkt. No. [27-1] at 15. Dexcom also argues that, even if the MDA does not expressly preempt Plaintiff's claims, it impliedly preempts them. Id. at 20. And Dexcom argues that, in any event, Plaintiff's claims are inadequately pled. Id. at 22–30. Dexcom moves for judgment on the pleadings on these bases. Plaintiff disagrees with each of Dexcom's arguments and argues that she should survive Dexcom's Motion to Dismiss. Dkt. No. [29]. After describing the legal standard that applies to Dexcom's Motion, the Court addresses the merits.

II. LEGAL STANDARD

"Judgment on the pleadings is appropriate when there are no material facts in dispute, and judgment may be rendered by considering the substance of the pleadings and any judicially noticed facts." Hawthorne v. Mac Adjustment, Inc., 140 F.3d 1367, 1370 (11th Cir. 1998) (citing Fed. R. Civ. P. 12(c)). The standard for assessing a motion for judgment on the pleadings is the same as the standard for a motion to dismiss under Rule 12(b)(6). Id.; Roma Outdoor Creations, Inc v. City of Cumming, 558 F. Supp. 2d 1283, 1284 (N.D. Ga. 2008).

In determining whether a complaint states a claim upon which relief can be granted, courts accept the factual allegations in the complaint as true and construe them in the light most favorable to the plaintiff. Hill v. White, 321 F.3d 1334, 1335 (11th Cir. 2003). To survive a motion to dismiss, a complaint must allege facts that, if true, "state a claim to relief that is plausible on its face." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quotations omitted). A claim is plausible where the plaintiff alleges factual content that "allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Id. The plausibility standard requires that a plaintiff allege sufficient facts "to raise a reasonable expectation that discovery will reveal evidence" that supports the plaintiff's claim. Bell Atl. Corp. v. Twombly, 550 U.S. 544, 556 (2007).

III. DISCUSSION

Dexcom seeks judgment on the pleadings and dismissal of Plaintiff's case for three reasons: (1) Plaintiff's claims are expressly preempted by the MDA; (2)

Plaintiff's claims are impliedly preempted; and (3) Plaintiff's claims are inadequately pled. Dkt. No. [27-1]. Plaintiff disagrees with each reason and argues that judgment on the pleadings is improper. Dkt. No. [29]. The Court addresses each reason in turn.

A. Express Preemption

Dexcom argues that Plaintiff's claims are expressly preempted by the MDA. Dkt. No. [27-1] at 15. The MDA includes an express preemption provision which provides that no "State may establish or continue in effect with respect to a device intended for human use any requirement" that is (1) different from, or in addition to, a "requirement applicable under [the MDA]" and (2) "which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under [the MDA]." 21 U.S.C. § 360k(a). Under this provision, then, courts must determine (1) whether the FDA "has established requirements applicable to" a medical device, and, if so, (2) whether a plaintiff's claims "are based upon [state law] requirements with respect to the device that are 'different from, or in addition to,' the federal ones, and that relate to safety and effectiveness." Riegel, 552 U.S. at 321–22 (citing 21 U.S.C. § 360k(a)). In this case, the issue is whether the FDA has established "requirements" applicable to the G6 System and whether Plaintiff's claims are based on state law "requirements with respect to the device" that conflict with or exceed the federal requirements. The Court takes each of these prongs in turn.

1. Federal Requirements

Dexcom argues that the FDA's De Novo classification of the G6 System imposes "requirements" under the MDA's preemption provision, 21 U.S.C. § 360k(a), which would preempt conflicting Georgia law requirements. Plaintiff disagrees. Neither party cites a case dealing with the FDA's De Novo classification system and preemption, so the Court examines relevant Supreme Court precedent for guidance on this issue.

The Supreme Court has twice interpreted the preemption provision's reference to federal "requirements." In Medtronic, Inc. v. Lohr, the Court held that the FDA did not impose requirements on a pacemaker that was approved through the § 510(k) substantial equivalence pathway. 518 U.S. 470. For guidance on the meaning of "requirement" in the preemption provision, the Court looked to an FDA regulation set forth at 21 C.F.R. § 808.1(d):

> State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements.

Given this guidance, the Supreme Court concluded that the § 510(k) substantial equivalence pathway did not impose "requirements." Lohr, 518 U.S. at 493–94. To support its conclusion, the Court noted two attributes of § 510(k) substantial equivalence review.

First, substantial equivalence review does not impose device-specific requirements. Lohr, 518 U.S. at 493 (observing that substantial equivalence "did not 'require' [the] pacemaker to take any particular form for any particular reason"); id. at 500 ("[F]ederal requirements must be 'applicable to the device' in question, and, according to the regulations, pre-empt state law only if they are 'specific counterpart regulations' or 'specific' to a 'particular device.'"). The Court contrasted the general regulations that apply to a device approved through substantial equivalence from "a case in which the Federal Government has weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers." Id.

And second, substantial equivalence review "is focused on *equivalence*, not safety." Lohr, 518 U.S. at 493 (citation omitted). The Court stressed that § 510(k) was an effort by Congress to give manufacturers seeking to enter the market a means by which "to compete, to a limited degree, with and on the same terms as manufacturers of medical devices that existed prior to 1976 [and were grandfathered in when the MDA was passed]." Id. at 494. Because substantial equivalence review, unlike premarket approval, does not weigh the risks and benefits of a device, the Court noted that it provides a lower level of protection to the public. Id. at 493. The non-specificity of substantial equivalence review and its attenuated level of risk analysis led the Court to conclude that it did not

impose "requirements" under the MDA's preemption provision as illuminated by the FDA's guidance. Id. at 493–94 ("[The FDA] did not 'require' Medtronics' pacemaker to take any particular form for any particular reason; the agency simply allowed the pacemaker, as a device substantially equivalent to one that existed before 1976, to be marketed without running the gauntlet of the PMA process.").

In Riegel v. Medtronic, Inc., a successor case to Lohr, the Supreme Court held that premarket approval imposed "requirements" under the MDA's preemption provision. 552 U.S. 312. The Court determined that premarket approval is a categorically different process from § 510(k) substantial equivalence. Unlike § 510(k) substantial equivalence, premarket approval is device-specific. Riegel, 552 U.S. at 322–23 ("Unlike general labeling duties, premarket approval is specific to individual devices."); id. at 323 ("[T]he FDA requires a device that has received premarket approval to be made with almost no deviations from the specifications in its approval application[.]"). Premarket approval also weighs the risks and benefits of a particular device to human safety. Id. at 323 (observing that premarket approval "is in no sense an exemption from federal safety review—it *is* federal safety review"); id. ("[P]remarket approval is focused on safety, not equivalence."). Last, the Supreme Court emphasized that the MDA restrains device makers from modifying their devices after approval. Id. at 319 ("Once a device has received premarket approval, the MDA forbids the manufacturer to make, without FDA permission, changes in design

specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." (citing 21 U.S.C. § 360e(d)(6)(A)(i))). These factors and other attributes of premarket approval mean that a device that has been so approved is subject to federal "requirements" for purposes of the preemption provision. Id. at 323 ("Premarket approval [] imposes 'requirements' under the MDA as we interpreted it in Lohr.").

The parties disagree over what these cases mean for the G6 System and its De Novo classification avenue to approval. Plaintiff argues that the Supreme Court's decisions in these cases mean that only the premarket approval process can ever amount to a "requirement" under the preemption provision. Dkt. No. [29] at 5–8. Plaintiff cites no authority for this proposition, and the Court disagrees with it. The Supreme Court has not held that *only* premarket approval rises to the level of a preempting requirement. It merely held that premarket approval imposed requirements on medical devices. Lower courts have considered other pathways to approval and have held that they, like premarket approval, imposed requirements on medical devices. Degelmann v. Advanced Med. Optics, Inc., 659 F.3d 835, 842 (9th Cir. 2011) ("[W]ith regard to the labeling at issue in this law suit, the FDA has promulgated specific requirements . . . ."), vacated, 699 F.3d 1103 (9th Cir. 2012);[2] Papike v. Tambrands Inc., 107 F.3d 737, 741 (9th 1997) ("Preemption results in this case because the FDA has

[2] Degelmann was vacated after the parties settled.

established specific counterpart regulations with respect to labeling tampons." (citing 21 C.F.R. § 808.1(d))); Kelsey v. Alcon Labs., Inc., No. 180902756, 2019 WL 1884225, at *10–11 (D. Utah Apr. 22, 2019) (holding that Guidance regarding labeling of contact lenses in a § 510(k) application imposed "requirements"). This Court agrees with these cases and disagrees with Plaintiff to the extent that a variety of FDA regulations may amount to "requirements" under the MDA.

Dexcom argues that the De Novo classification process through which the G6 System was approved imposes preemptive "requirements." Dkt. No. [27-1] at 16. Dexcom notes that, following De Novo review, the FDA imposed "special controls" to regulate the G6 System, which apply "to the design, testing, manufacture, and labeling of the device." Id.

The Court cannot hold at this stage that the G6 System is subject to FDA "requirements" within the meaning of the preemption provision. Dexcom's case for preemption turns on the nature of the De Novo classification process. But that process, and the regulations for continuous glucose monitoring systems that are to be published through that process, have not yet been codified. See United States Food & Drug Administration, De Novo Classification Requests (2019) (noting regarding De Novo classification that "currently no regulations exist for this program"), https://www.fda.gov/medical-devices/premarket-submissions/de-novo-classification-request; Dkt. No. [27-1] at 12 n.7 (noting that the Class II controls for continuous glucose monitoring systems have not yet been codified). Without laws and regulations directly on point, the Court is left to

determine whether the FDA has imposed "requirements" on the G6 System *in this case*. That determination requires the Court to consider factors like whether the FDA imposed device-specific requirements, whether Dexcom may make changes to its G6 System once De Novo review is complete, and whether Dexcom has ongoing reporting requirements regarding the G6 System. These are issues for which the Court must look beyond the four corners of the Complaint.

If the Court were to hold that De Novo classification preempts State laws and common-law causes of action, that holding would "effect a radical curtailment of state common-law suits seeking compensation for injuries caused by defectively designed or labeled medical devices." Riegel, 552 U.S. at 333 (Ginsburg, J., dissenting). While the Supreme Court has held that certain forms of FDA regulation may radically curtail plaintiffs' suits in this way, id. at 321, it has done so with the robust data necessary to conduct "a careful comparison between the allegedly pre-empting federal requirement and the allegedly pre-empted state requirement to determine whether they fall within the pre-emptive scope of the statute and regulations" Lohr, 518 U.S. at 500. At this early stage of the case, the Court lacks the information necessary to conduct this "careful comparison" and hold, as a matter of law, that the FDA has preempted Plaintiff's State law causes of action. See Lohr, 518 U.S. at 487 ("[B]ecause the States are independent sovereigns in our federal system, we have long presumed that Congress does not cavalierly pre-empt state-law causes of action."). Defendant

has not met its burden on this record for Plaintiff's claims to be dismissed on this basis.

2. State Law Requirements

The second prong of MDA preemption requires the Court to consider whether Plaintiff's claims "are based upon [State law] requirements with respect to the device that are 'different from, or in addition to,' the federal ones, and that relate to safety and effectiveness." Riegel, 552 U.S. at 321–22 (citing 21 U.S.C. § 360k(a)). Since the Court lacks information sufficient to determine whether the FDA has imposed "requirements," the Court lacks a basis for comparison to the ostensible Georgia law "requirements" that provide Plaintiff with her causes of action. The Court therefore declines to address the second prong of the preemption test.

Accordingly, the Court declines to hold at this stage that Plaintiff's claims are expressly preempted under the MDA. The Court emphasizes that this decision does not eliminate the possibility of preemption, only the appropriateness of preemption at this early stage with so little information about how the G6 System was approved.

B. Implied Preemption

Dexcom also argues that Plaintiff's claims are impliedly preempted. Dkt. No. [27-1] at 20. It argues that, because the FDA's regulations prevent it from making certain changes to the G6 System, it cannot alter the G6 System in the way that Plaintiff's Georgia law claims would require it to. Id. Plaintiff disagrees.

Dkt. No. [29] at 8. She argues that Dexcom cannot rely on the possibility that the FDA will reject proposed changes and that, in fact, Dexcom may change the G6 System under the FDA's regulations. Id.

Conflict preemption applies "when it is 'impossible for a private party to comply with both state and federal requirements.'" Merck Sharp & Dohme Corp. v. Albrecht, 139 S. Ct. 1668, 1672 (2019 (quoting Mut. Pharm. Co. v. Bartlett, 570 U.S. 472, 480 (2013)). This is because "it has long been settled that state laws that conflict with federal law are without effect." Mut. Pharm. Co., 570 U.S. at 480. "The question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it." PLIVA v. Mensing, 564 U.S. 604, 618 (2011). "Impossibility pre-emption is a demanding defense." Merck Sharp & Dohme Corp., 139 S. Ct. at 1678 (quoting Wyeth v. Levine, 555 U.S. 555, 573 (2009)).

The Court declines to hold that Plaintiff's claims are impliedly preempted as a matter of law. As the Court previously noted, there is insufficient information at this point to determine exactly the restrictive and preemptive effect of a De Novo classification. At the very least, Plaintiff alleges that after De Novo classification a manufacturer need only "submit a 510(k) notice to the FDA" to make changes to device. Dkt. No. [16] ¶ 42. This suggests that Dexcom might make the changes necessary to comply with Georgia law.

The Court notes that in an analogous context—that of pharmaceutical regulation—the Supreme Court has held that a defendant must show through

"'clear evidence' that the FDA would not have approved the warning that state law requires." Merck Sharp & Dohme Corp., 139 S. Ct. at 1676 (citing Wyeth, 555 U.S. at 571). "[T]he 'possibility of impossibility [is] not enough.'" Id. at 1678 (quoting PLIVA, Inc. v. Mensing, 564 U.S. 604, 625 (2011)). Impossibility preemption requires more than a showing that "the laws of one sovereign permit an activity that the laws of the other sovereign restrict or even prohibit." Id. And when the FDA provides manufacturers with an avenue to change a device, "a [] manufacturer will not ordinarily be able to show that there is an actual conflict between state and federal law such that it was impossible to comply with both." Id. at 1679. Here, Dexcom has failed to show through "clear evidence" that it cannot alter the G6 System.

The Court does not rule out impossibility preemption as a matter of law at this stage. It only finds that Dexcom has not carried its burden of showing that it could not possibly adapt its device to the requirements that Georgia law might impose. While this question is ultimately "one for the judge, not a jury," id., it is a question that requires the parties to marshal evidence that is not in the record at this stage. Id. at 1680 ("We understand that sometimes contested brute facts will prove relevant to a court's legal determination about the meaning and effect of an agency decision."). Accordingly, the Court declines to dismiss Plaintiff's case on the basis of impossibility preemption.

C. Adequacy of Pleading

Dexcom also argues that Plaintiff's claims are inadequately pled. Dkt. No. [27-1] at 17–25. This includes Plaintiff's claims for strict liability (manufacturing defect and design defect), failure to warn, and punitive damages. Plaintiff contests Dexcom's arguments. Dkt. No. [29] at 10–15. The Court addresses each claim in turn.

1. Strict Liability for Manufacturing and Design Defects

Dexcom argues that Plaintiff's claims based on the G6 System's product defects are inadequately pled. Dkt. No. [27-1] at 22.[3] Dexcom argues that Plaintiff "provides no specific factual allegations" that the manufacturing of Mr. Tuttle's G6 system deviated from objective criteria or from its design. Id. Dexcom also argues that Plaintiff has failed to plead any design defect. Id. at 23–24. Plaintiff disagrees and argues that she has alleged manufacturing and design defects in the G6 System. Dkt. No. [29] at 11.

Georgia law imposes strict liability for product defects. O.C.G.A. § 51-1-11(b)(1); Sharp v. St. Jude Med., S.C., Inc., 838 F. App'x 462, 467 (11th Cir. 2020) (unpublished) (applying Georgia law). Manufacturers are liable for injuries that take place "because the property when sold by the manufacturer was not merchantable and reasonably suited to the use intended, and its condition when

[3] Plaintiff's product-defect claims include negligence and strict liability. Dexcom parses these claims through the lens of design defect, manufacturing defect, and failure to warn. Plaintiff follows this approach in response, and so the Court does the same here.

sold is the proximate cause of the injury sustained." O.C.G.A. § 51-1-11(b)(1). "There are three general categories of product defects: manufacturing defects, design defects, and marketing/packaging defects." Banks v. ICI Americas, Inc., 264 Ga. 732, 450 S.E.2d 671, 672 (1994).

Plaintiff has adequately alleged that the G6 System was defectively manufactured. Under Georgia law, Plaintiff must "allege the existence of a specific manufacturing defect that proximately caused the harm." Sharp, 838 F. App'x at 466 (quoting Brazil v. Janssen Rsch. & Dev. LLC, 196 F. Supp. 3d 1351, 1357 (N.D. Ga. 2016)). "[B]y definition, a manufacturing defect will always be identifiable as a deviation from some objective standard or a departure from the manufacturer's specifications established for the creation of the product." Id. "At the motion to dismiss stage, a plaintiff 'need only allege [] a deviation and that the deviation was the proximate cause of the injury.'" Id. (quoting Morgan v. Dick's Sporting Goods, Inc., 359 F. Supp. 3d 1283, 1292 (N.D. Ga. 2019)). "[T]he existence of a defect can be shown through circumstantial evidence alone[.]" Id. at 467.

Plaintiff has alleged that the G6 System failed in eleven specific ways. Dkt. No. [16] ¶ 93. She alleges that the G6

- Failed to prevent clinically significant gaps in sensor data availability that prevented digitally connected devices from achieving their intended use.
- Failed to ensure secure and reliable means of data transmission to provide real-time glucose readings at clinically meaningful time intervals to devices intended to receive the glucose data.

- Failed to ensure that the intended user can use the device safely and obtain the expected glucose measurement accuracy.
- Failed to give a Low alert when the user's glucose level fell below 70 mg/dl.
- Failed to give an Urgent Low Soon alert when the user's glucose levels were falling fast and would be 55 mg/dl in less than 20 minutes.
- Failed to give an Urgent Low alarm when the user's glucose level fell below 55 mg/dl and to repeat every 30 minutes.
- Failed to give a Sensor Error alert when a sensor error occurred.
- Failed to give a Transmitter Error alert when the transmitter was not working.
- Failed to give a Signal Loss alert when signal was lost.
- Failed to give a No Readings alert when no readings were detected.
- Failed to give a sufficient Sensor Error, Transmitter Error, Signal Loss, or No Readings alert.

Plaintiff alleges that these failures flowed from manufacturing defects. Id. And Plaintiff alleges that the failure of the G6 System to alert Mr. Tuttle of his hypoglycemic event caused him not to recognize the event, which in turn led to the anoxic brain injury and respiratory failure that killed him. Id. ¶ 97. The Court finds that these allegations satisfy Plaintiff's burden of identifying, through "circumstantial evidence," Sharp, 838 F. App'x at 467, a manufacturing defect without which the G6 System would not have failed. She has also alleged "that this deviation was the proximate cause of the injury[.]" Jones v. Amazing Prods.,

Inc., 231 F. Supp. 2d 1228, 1236 (N.D. Ga. 2002). These allegations "satisfy the elements of the [manufacturing defect] claim." Id.

Plaintiff has also adequately alleged design defects. "[A] design defect claim posits that there is a problem with the entire product line[.]" In re Mentor Corp. ObTape Transobturator Sling Prod. Liab. Litig., 711 F. Supp. 2d 1348, 1365 (M.D. Ga. 2010). In Georgia, a claim for design defect "calls for the finder of fact to employ a loose balancing test to determine whether the manufacturer properly designed the product." Id. In that test, "the risks inherent in a product design are weighed against the utility or benefit derived from the product." Banks, 264 Ga. at 734, 450 S.E.2d 671. "The risk-utility analysis incorporates the concept of 'reasonableness,' i.e., whether the manufacturer acted reasonably in choosing a particular product design, given the probability and seriousness of the risk posed by the design, the usefulness of the product in that condition, and the burden on the manufacturer to take the necessary steps to eliminate the risk." Id.

Here, Plaintiff alleges the same eleven failures as design defects that she lists as flowing from manufacturing defects. Dkt. No. [16] ¶ 92. The Court finds that these allegations are sufficient at this stage for Plaintiff to carry her burden of pleading that the G6 System was unreasonably dangerous as designed. Given the fact-intensive nature of this test, "determination of a product's risks and benefits as a matter of law . . . 'will rarely be granted in design defect cases when any of these elements is disputed.'" Ogletree v. Navistar Int'l Transp. Corp., 271 Ga. 644, 646, 522 S.E.2d 467 (1999). The Court refrains from conducting this

fact-intensive balancing test when Plaintiff's allegations are otherwise legally sufficient.

Dexcom emphasizes regarding manufacturing and design defects that the FDA's regulations provide a basis to dismiss Plaintiff's strict-liability claim. Dkt. No. [32] at 12–13. This is because, Dexcom argues, the FDA established manufacturing and design controls for the G6 System intended to ensure that the G6 System is reasonably safe. Setting aside the issue of preemption, Dexcom cites no authority indicating that the FDA's determination of the G6 System's safety decides that issue as a matter of law. Accordingly, the Court finds that Plaintiff's claims for manufacturing and design defects are adequately pled.

2. Failure to Warn

Dexcom also argues that Plaintiff has failed to allege that Dexcom is liable for its failure to warn of risks inherent in the G6 System. Dkt. No. [27-1]. Dexcom raises three deficiencies to support dismissal: (1) Plaintiff's allegations that Dexcom's warnings were "not sufficient" are conclusory; (2) in any event, Dexcom's User Guide for the G6 did properly warn Plaintiff of the risks which she claims it failed to warn her about; and (3) Plaintiff has failed to allege that Mr. Tuttle read the G6 System's warnings. Dexcom also argues that the duty to warn extended to Mr. Tuttle's physician, not to Mr. Tuttle, under the "learned intermediary" doctrine. Id. at 22 n.13. Plaintiff responds that she has alleged that Dexcom failed to adequately warn Mr. Tuttle of 12 defects. Dkt. No. [29] at 13–14.

"Under Georgia law, a manufacturer has a duty to warn of nonobvious foreseeable dangers from the normal use of its product." Thornton v. E.I. Du Pont De Nemours and Co., 22 F.3d 284, 289 (11th Cir. 1994) (citing Stovall & Co. v. Tate, 124 Ga. App. 605, 184 S.E.2d 834, 837 (1971)). "The duty to warn an end user of a risk associated with product use arises when the manufacturer knows or reasonably should know of a danger arising from product use." Wheat v. Sofamor, S.N.C., 46 F. Supp. 2d 1351, 1363 (N.D. Ga. 1999) (citing Chrysler Corp. v. Batten, 264 Ga. 723, 724, 450 S.E.2d 208, 211 (1994)). Under Georgia's "learned intermediary doctrine, the manufacturer of a prescription drug or medical device does not have a duty to warn the patient of the dangers involved with the product, but instead has a duty to warn the patient's doctor, who acts as a learned intermediary between the patient and the manufacturer." McCombs v. Synthes (U.S.A.), 277 Ga. 252, 253, 587 S.E.2d 594, 595 (2003).[4]

A failure to warn claim includes three elements: (1) "that the defendant had a duty to warn"; (2) "that the defendant breached that duty"; and (3) "that the breach proximately caused the plaintiff's injury." Dietz v. Smithkline Beecham

[4] Dexcom argues that Plaintiff's claim should be dismissed under the learned intermediary doctrine because she has not alleged that Dexcom failed to warn Mr. Tuttle's physician. But Plaintiff's failure-to-warn allegations are not couched in terms of Dexcom's failure to warn Mr. Tuttle specifically. Rather, Plaintiff alleges, for example, that "Dexcom failed to adequately warn of the above design and manufacturing defects." Dkt. No. [16] ¶ 94. The Court must read the Amended Complaint in the light most favorable to Plaintiff, and in that light, Plaintiff's allegations of failure to warn are broad enough to include Mr. Tuttle's physician.

Corp., 598 F.3d 812, 815 (11th Cir. 2010). "Whether a duty to warn exists thus depends upon [the] foreseeability of the use in question, the type of danger involved, and the foreseeability of the user's knowledge of the danger." Battersby v. Boyer, 241 Ga. App. 115, 117, 526 S.E.2d 159, 162 (1999) (quoting Yaeger v. Stith Equip. Co., 177 Ga. App. 835, 836, 341 S.E.2d 492 (1986)). "Such matters generally are not susceptible of summary adjudication and should be resolved by a trial in the ordinary manner." Id.

Plaintiff alleges that Dexcom failed to adequately warn Mr. Tuttle of the 11 design and manufacturing defects and that it failed to warn him that in a hypoglycemic event he might be left without a Glucose Alert (indicating low glucose) or a System Alert (indicating that the G6 stopped working). Dkt. No. [29] at 13–14; Dkt. No. [16] ¶¶ 94–95, 105–06. As previously discussed, the 11 design and manufacturing defects include the following:

- Failed to prevent clinically significant gaps in sensor data availability that prevented digitally connected devices from achieving their intended use.
- Failed to ensure secure and reliable means of data transmission to provide real-time glucose readings at clinically meaningful time intervals to devices intended to receive the glucose data.
- Failed to ensure that the intended user can use the device safely and obtain the expected glucose measurement accuracy.
- Failed to give a Low alert when the user's glucose level fell below 70 mg/dl.

- Failed to give an Urgent Low Soon alert when the user's glucose levels were falling fast and would be 55 mg/dl in less than 20 minutes.

- Failed to give an Urgent Low alarm when the user's glucose level fell below 55 mg/dl and to repeat every 30 minutes.

- Failed to give a Sensor Error alert when a sensor error occurred.

- Failed to give a Transmitter Error alert when the transmitter was not working.

- Failed to give a Signal Loss alert when signal was lost.

- Failed to give a No Readings alert when no readings were detected.

- Failed to give a sufficient Sensor Error, Transmitter Error, Signal Loss, or No Readings alert.

Dexcom argues that the User Guide to the G6 System includes the very warnings that Plaintiff alleges Mr. Tuttle never received. Dkt. No. [27-1] at 25–26. Dexcom points to the following entries in the User Guide:

1. The Risks and Benefits Chapter (Chapter 3) includes a warning about the risk of "[n]ot getting your alarm/alerts." Dkt. No. [16-1] at 37. Specifically, the Guide warns, "If you aren't getting your alarm/alerts, you could have severe low or high glucose without know it." Id. Further, "If you get a system error—such as No Readings, Sensor Error, or Signal Loss—you won't get G6 readings or alarms/alerts." Id. at 38;

2. The section describing Alerts addresses cases of "Signal Loss Alert." Id. at 147. "This tells you when you're not getting G6 readings. . . . During signal loss, use your meter to check your glucose and make any treatment decisions." Id.;

3. The Troubleshooting Chapter (Chapter 14) includes an entry for "No G6 Readings: No Readings Alert." Id. at 229. It describes

the "Problem" as "[n]ot getting G6 readings for the last 20 minutes." Id. The first "Solution" is, "No glucose alarms/alerts or G6 readings until fixed. Use meter." Id.;

4. The same chapter includes an entry for "No G6 Readings: Signal Loss Alert." Id. at 233. It describes the "Problem" as "[n]ot getting G6 readings" and "[d]isplay device and transmitter not connecting." Id. The first "Solution" is, "Use meter. No glucose alarm/alerts or G6 readings until fixed." Id.;

5. The User Guide contains an "Appendix F: Technical Information," which describes the G6 System's performance characteristics. Id. at 293. Dexcom asserts that this section "explicitly identifies the frequency and duration of gaps in sensor data, and of true, false, missed, and correct alert rates . . . ." Dkt. No. [27-1] at 26.

While there is some overlap between the warnings that Plaintiff alleges ought to have been given and the warnings provided in the User Guide, that does not defeat Plaintiff's claim as a matter of law. Plaintiff has stated a claim under Georgia law because she has alleged that Dexcom's warnings were inadequate. Dkt. No. [16] ¶¶ 94, 105. Georgia courts have emphasized that even when a manufacturer warns a buyer of a danger, fact issues may remain as to the warning's adequacy. "It is . . . a jury question whether or not the manufacturer was negligent in failing to place a warning in such *position*, color and size print or to use symbols which would call the user's attention to the warning or cause the user to be more likely to read the label and warning than not." Battersby, 526 S.E.2d at 163 (quoting Wilson Foods Corp. v. Turner, 218 Ga. App. 74, 75, 460 S.E.2d 532 (1995)); Thornton, 22 F.3d at 289 ("The general rule in Georgia is that the adequacy of the warning is an issue for the jury."); Key Safety Sys., Inc. v.

Bruner, 334 Ga. App. 717, 721, 780 S.E.2d 389, 393 (2015) ("[T]he argument made by Key is one of adequacy, which would be a fact question for the jury."). "Failure to communicate an adequate warning involves such questions, as are here at issue, as to location and presentation of the warning." Wilson, 460 S.E.2d at 534. And the requirement that warnings be adequate also applies to physician-directed warnings under the learned intermediary doctrine: "[U]nder the learned intermediary doctrine, the manufacturer's warnings to the physician must be adequate or reasonable under the circumstance of the case." McCombs, 277 Ga. at 253.

Courts have sometimes pointed out that adequacy takes two forms. "Where a duty to warn arises, . . . '[t]his duty may be breached by (1) failing to adequately communicate the warning to the ultimate user or (2) failing to provide an adequate warning of the product's potential risks." Wilson, 460 S.E.2d at 534 (quoting Thornton, 22 F.3d at 289). Each of these issues is a jury question. Thornton, 22 F.3d at 289 ("Whether adequate efforts were made to communicate a warning to the ultimate user and whether the warning if communicated was adequate are uniformly held questions for the jury.").

In Battersby, for example, a manufacturer warned consumers about the rollover risk of an ATV, and the plaintiff was injured in a rollover. 241 Ga. App. 115, 526 S.E.2d 159. The Georgia Court of Appeals held that this warning discharged the ATV *seller's* responsibility because the seller was entitled to rely on the adequacy of the manufacturer's warning. 526 S.E.2d at 162–63 ("[T]he

seller in that circumstance does not have to second-guess whether the manufacturer's warning was adequate."). But the warning did not absolve the manufacturer because "an issue of fact remain[ed] concerning the adequacy of the warning placed on the ATV . . . ." Id. at 162; id. at 163 ("[T]he consumer's challenge to the adequacy of the manufacturer's warning is not foreclosed."); see also Camden Oil Co. v. Jackson, 270 Ga. App. 837, 841, 609 S.E.2d 356, 359 (2004) ("The warning at issue here was located on a column in full view of the customers at the gasoline pumps. . . . [But] without any visual clues or topically relevant headings, a customer would not realize the warning applied to portable containers."). So even though the manufacturer had included a warning about rollover risk, that warning did not discharge the manufacturer's liability as a matter of law where the adequacy of the warning was still at issue. Id.

And in Chambers, a Middle District of Georgia case applying Georgia law, the court held that a fact issue prevented summary judgment despite a product warning that related to the injury suffered. Chambers v. Boehringer Ingelheim Pharms., Inc., No. 4:15-cv-0068 (CDL), 2018 WL 849081 (M.D. Ga. Jan. 2, 2018). The decedent there was prescribed a blood-thinner called Pradaxa, and sixteenth months after the prescription, he died from a gastrointestinal bleed. Id. at *1. The defendant-manufacturer of Pradaxa cited a warning label "that (1) identifie[d] the risk of bleeding; (2) explain[ed] that bleed risk increased with age; (3) note[d] that elderly subjects in [a] trial had higher incidence of bleeding on Pradaxa than Warfarin; and (4) explain[ed] that anticoagulant activity and

half-life of Pradaxa are increased in patients with moderate renal impairment." Id. at *11. Still, a fact issue remained on the *adequacy* of the warning because the plaintiff's experts "opine[d] that the label should have called for blood level monitoring and that the lack of monitoring language led to greater risk from over-anitcoagulation than the label conveyed." Id. As in Battersby and Camden, judgment for the defendant was improper because "a jury could conclude that [the defendant's] label did not completely disclose the risks involved . . . ." Id.

Here, Plaintiff lists twelve specific risks that she says Dexcom should have warned her husband of. Dkt. No. [16] ¶¶ 92, 93, 104. She alleges, under her strict liability and negligence counts, that Dexcom "failed to adequately warn of [these] defects." Id. ¶¶ 94, 105. She identifies the pages in the User Guide where the warnings should have appeared. Id. ¶¶ 96, 107. The Court finds these allegations sufficient to state a claim and to survive Dexcom's Motion to Dismiss, especially since "[t]he general rule in Georgia is that the adequacy of the warning is an issue for the jury." Thornton, 22 F.3d at 289. And although Dexcom argues that Plaintiff may not recover because she has not alleged that Mr. Tuttle read the warning, "[f]ailure to read a warning does not bar recovery when the plaintiff is challenging the adequacy of the efforts of the manufacturer or seller to communicate the dangers of the product to the buyer or user." Wilson, 460 S.E.2d at 534 (citing Thornton, 22 F.3d at 290).

Another feature of Georgia law reinforces the Court's conclusion that dismissal is improper. Georgia law imposes a continuing post-sale duty to warn

upon manufacturers. See O.C.G.A. § 51-1-11(c) ("Nothing contained in this subsection shall relieve a manufacturer from the duty to warn of a danger arising from use of a product once that danger becomes known to the manufacturer."); Batten, 450 S.E.2d at 213 ("That '[n]othing' relieves a manufacturer from the duty to warn reflects the legislature's recognition of the possibility that this duty may not emerge until long after the statute of repose has extinguished any cause of action arising out of the product's sale; that the duty to warn arises 'once th[e] danger becomes known' reflects the existing case law with its actual or constructive knowledge standard."). Citing Batten, the Eleventh Circuit has emphasized that "[t]his duty to warn is a continuing one and may arise 'months, years, or even decades after the date of the first sale of the product.'" Watkins v. Ford Motor Co., 190 F.3d 1213, 1219 (11th Cir. 1999) (quoting Batten, 450 S.E.2d at 211). In Watkins v. Ford, for example, the Eleventh Circuit found record evidence of Ford's failure to warn when post-sale studies showed that one of its vehicles had a high rollover risk but "Ford failed to issue any post-sale warnings regarding these stability problems." Id.

This continuing duty is relevant here because it enhances the possibility that Dexcom's warnings were inadequate. Plaintiff alleges that Dexcom had notice from other consumers that the G6 System and its predecessors had issues. Dkt. No. [16] ¶ 19 ("[T]housands of users have notified Dexcom that the alarms in its predecessor models, the G5 and G4 Platinum CGM, are unreliable and inadequate."); id. ¶ 20 ("In numerous cases, users have reported that the sensors,

transmitters and/or display devices on the G6 System and its predecessors fail to work. For example, on May 7, 2019, the day Michael Tuttle was prescribed the G6 System, [] Dexcom received (and later confirmed) user reports that a sensor failed prematurely, a transmitter failed, and a loss of connection occurred."); id. ¶ 21 ("Numerous users have warned Dexcom that the G6 System and its predecessors will often not sound during severe hyperglycemic and hypoglycemic events. For example, [] on May 7, 2019, Dexcom also received a report that a patient's blood sugar became dangerously low when the G6 failed to provide an alert."); id. ¶ 22 ("Numerous users have warned Dexcom that the G6 System's predecessors will test properly but then fail to sound when users are experiencing dangerously high or low glucose levels."). These post-sale issues may impact the adequacy of Dexcom's existing warnings, and they contribute to the factual dispute whether the warnings that reached Mr. Tuttle or his physician were adequate.

Accordingly, the Court finds that Plaintiff has sufficiently pled her claim that Dexcom failed to adequately warn her husband of defects in the G6 system.

3. Punitive Damages

Dexcom argues that Plaintiff's claim for punitive damages should be dismissed for two reasons: (1) the claim is plead in a conclusory way; and (2) the claim is derivative of her underlying tort claims, which Dexcom argues should be dismissed. Dkt. No. [27-1] at 27–28. Plaintiff does not respond to Dexcom's argument that her punitive damages claim should be dismissed. Dkt. No. [29].

Since Plaintiff does not respond, Dexcom argues that Plaintiff has waived her punitive damages claim. Dkt. No. [32] at 16.

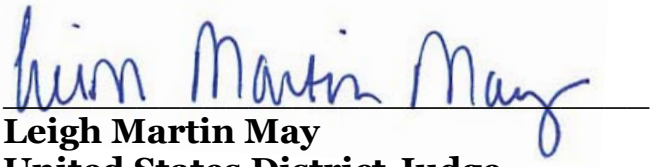
The Court agrees with Dexcom that Plaintiff has waived her claim. Plaintiff does not address punitive damages in her Response Brief. Dkt. No. [29]. "'[A] party's failure to respond to any portion or claim in a motion indicates such portion, claim or defense is unopposed.'" Jones v. Bank of Am., N.A., 564 F. App'x 432, 434 (11th Cir. 2014) (per curiam) (unpublished) (quoting Kramer v. Gwinnett County, 306 F. Supp. 2d 1219, 1221 (N.D. Ga. 2004)). And "'[w]hen a party fails to respond to an argument or otherwise address a claim, the Court deems such argument or claim abandoned.'" Id. (quoting Hudson v. Norfolk S. Ry. Co., 209 F. Supp. 2d 1301, 1324 (N.D. Ga. 2001)). Accordingly, the Court deems Plaintiff's claim for punitive damages abandoned, and it is **DISMISSED.**

IV. CONCLUSION

Based upon the foregoing, Defendant Dexcom's Motion for Judgment on the Pleadings [27] is **GRANTED in part** and **DENIED in part**. Plaintiff's claim for punitive damages is **DISMISSED**. Plaintiff's remaining claims survive.

Defendant's request for oral argument [27] is **DENIED**.

IT IS SO ORDERED this 20th day of May, 2021.



Leigh Martin May
United States District Judge